IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Claes Wallen	Art Unit	: 3761
Serial No.	: 10/063,288	Examiner	: Leslie R. Deak
Filed	: April 8, 2002	Conf. No.	: 2442
Title	: DEVICE AND METHOD FOR MIXING MEDICAL FLUIDS		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 CFR 1.705(b)

Applicants hereby petition for reconsideration of the Patent Term Adjustment (PTA) accorded the above-referenced patent application. Attached herewith is a copy of the Notice of Allowance including a Determination of Patent Term Adjustment under 35 U.S.C. 154(b), mailed October 28, 2008, for the above-referenced application. The Notice of Allowance states that the Patent Term Adjustment at allowance is 183 days. Correction of the Patent Term Adjustment calculation to increase PTO Delay from 632 days to 795 days, decrease Applicant Delay from 449 days to 278 days, and to increase Total PTA from 183 to 517 days, is respectfully requested.

REVIEW OF PATENT TERM ADJUSTMENT CALCULATION

A review of the Patent Term Adjustment History in the PAIR system shows that the United States Patent and Trademark Office (PTO) calculated the Patent Term Adjustment (PTA) as follows:

1) The PTO mailed a delayed 14-month first non-final Office Action on September 22, 2004, thereby according a PTO Delay of 472 days. Applicants' concur with this patent term adjustment calculation.

2) Applicants filed a response to a second non-final Office Action on July 25, 2005 (received at the PTO on July 25, 2005). A Petition for Review by the Office of Petitions was mailed December 23, 2005 that shows a PTO stamp with a date of July 25, 2005 as the date of receipt. Applicants were accorded a delay of 237

CERTIFICATE OF MAILING BY EFS-WEB FILING:

I hereby certify that this paper was filed with the Patent and Trademark Office using the EFS-WEB system on this date: January 27, 2009

days for a delayed response. Applicants respectfully submit that the PTO's calculation of Applicant Delay contains an error and that the correct Applicant Delay is 82 days, as outlined further below.

3) Applicants filed a delayed Petition for review by the Office of Petitions on December 23, 2005 (received at the PTO on December 27, 2005). Applicants were not accorded a delay for a delayed response. Applicants respectfully submit that the PTO's calculation of Applicant Delay contains an error and that the correct Applicant Delay is 50 days, as outlined further below.

4) The PTO mailed a delayed non-final Office Action on October 4, 2006, thereby according a PTO Delay of 313 days. PTO delay was accorded a delay of 160 days. Applicants respectfully submit that the PTO's calculation of PTO Delay contains an error and that the correct PTO Delay is 313 days, as outlined further below.

5) Applicants filed a delayed response to a non-final Office Action on February 5, 2007 (received at the PTO on February 5, 2007). Applicants were accorded a delay of 32 days for a delayed response. Applicants concur with this patent term adjustment calculation.

6) The PTO maintains the PTO mailed a Final Rejection on April 11, 2007. However, a Notice of Restarted Response was mailed June 15, 2007, thereby according a PTO Delay of 10 days. PTO delay was not accorded a delay. Applicants respectfully submit that the PTO's calculation of PTO Delay contains an error and that the correct PTO Delay is 10 days, as outlined further below.

7) Applicants filed a delayed Request for Continued Examination on October 8, 2007, (received at the PTO on October 8, 2007). Applicants were accorded a delay of 89 days for a delayed response. Applicants respectfully submit that the PTO's calculation of Applicant Delay contains an error and that the correct Applicant Delay is 23 days, as outlined further below.

8) Applicants filed a delayed response to a non-final Office Action on June 5, 2008, (received at the PTO on June 5, 2008). Applicants were accorded a delay of 91

days for a delayed response. Applicants concur with this patent term adjustment calculation.

9) The PTO calculates a total PTO Delay of 632 days and a total Applicant Delay of 449 days, for a total PTA of 183 days. Applicants respectfully submit that the PTO's calculation of PTO Delay and Applicant Delay contains an error and that the correct total PTO Delay is 795 days, and Applicant Delay is 278 days, thus yielding a total PTA of 517 days.

MISCALCULATION OF PTO DELAY

A. PTO Delay Should Be Calculated from November 25, 2005 to October 4, 2006 Due to Delayed Action After Abandonment

On October 4, 2006, the PTO mailed a non-final Office Action (copy enclosed). The PTO calculates a delay of 160 days due to an error in entering the date of the Applicant Response as December 27, 2005, instead of the correct date, as July 25, 2005. As the PTO's complete response was not received within four months of the Applicants' action, the PTO should be assessed additional delay for the delayed response to the Applicant.

B. PTO Delay Should Be Calculated After Delayed Final Rejection

On June 15, 2007, the PTO mailed a Final Rejection (copy enclosed). The PTO does not calculate a delay due to an error in entering the mailing date of the Final Rejection as April 11, 2007, instead of the correct date, as June 15, 2007. As the PTO's complete response was not received within four months of the Applicants' action, the PTO should be assessed additional delay for the delayed response to the Applicant.

MISCALCULATION OF APPLICANT DELAY

A. Applicant Delay Should Not Be Calculated from December 27, 2005, as Applicants Filed a Complete Response on July 25, 2005

On July 25, 2005, Applicants mailed a Response to a non-final Office Action. The PAIR system does not indicate that the PTO received Applicants' response; however, a return receipt postcard was received with the PTO's date stamp of July 25, 2005. The PTO calculates a delay due to an error in entering the mailing date of the Response as December 27, 2005, instead of the

correct date, as July 25, 2005. Applicants therefore respectfully request to decrease Applicant Delay from 237 days to 82 days.

B. Applicant Delay Should Be Considered After a Delayed Petition for Review by the Office of Petitions

On September 7, 2005, the PTO mailed a Notice of Abandonment (copy enclosed). Applicants submitted a delayed Petition for Review by the Office of Petitions on December 27, 2005 (copy enclosed). Applicants should therefore be assessed delay for the delayed response to the PTO's Notice.

C. Applicant Delay Should Not be Calculated from July 11, 2007, as the PTO Mailed a Notice of Restarted Response Period on June 15, 2007

The PTO calculated 89 days of Applicant Delay due to a delayed Request for Continued Examination. However, the days are calculated from the date July 11, 2007, assuming the Final Rejection was mailed on April 11, 2007. The PTO mailed a Notice of Restarted Response Period on June 15, 2007; therefore Applicant Delay should be calculated from September 15, 2007. Applicants therefore respectfully request to decrease Applicant Delay from 89 days to 23 days.

DOCUMENTS ENCLOSED

A copy of each of the following documents is provided herein:

1) Non-Final Office Action mailed October 4, 2006;
2) Final Rejection mailed June 15, 2007;
3) Notice of Abandonment mailed September 7, 2005; and
4) Petition for Review by the Office of Petitions mailed December 23, 2005.

REMARKS

In consideration of the events described above, Applicants believe the PTA calculation of 183 days is incorrect. Applicants respectfully request recalculation of the patent term adjustment in the following manner:

1) Total PTO Delay should be calculated as 795 days (472 days for a delayed first non-final Office Action; 313 days for a delayed non-final Office Action; 10 days for a delayed Final Rejection); and

2) Total Applicant Delay should be calculated as 278 days (82 days for a delayed response to a non-final Office Action; 50 days for a delayed Petition for Review by the Office of Petitions; 32 days for a delayed response to a non-final Office Action; 23 days for a delayed Request for Continued Examination; 91 days for a delayed response to a non-final Office Action).

Therefore, Applicants respectfully request the addition of 163 days of PTO Delay, thus increasing PTO Delay from 632 days to 795 days, and the removal of 171 days of Applicant Delay, thus decreasing Applicant Delay from 449 days to 278 days and increasing the Total PTA from 183 to 517 days.

All fees are being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply all charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 1/27/09

/Kirk Dorius/
Kirk Dorius
Reg. No. 54,073

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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
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NOTICE OF ALLOWANCE AND FEE(S) DUE

26191 7590 10/28/2008

FISH & RICHARDSON P.C.
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
DEAK, LESLIE R	
ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 10/28/2008

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,288	04/08/2002	Claes Wallen	19497-011001 / P16488US00	2442

TITLE OF INVENTION: DEVICE AND METHOD FOR MIXING MEDICAL FLUIDS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$755	$300	$0	$1055	01/28/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

Notice of Allowability	Application No.	Applicant(s)	
	10/063,288	WALLEN ET AL.	
	Examiner	Art Unit	
	LESLIE R. DEAK	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *AF amendment mailed 8 October 2008*.

2. ☒ The allowed claim(s) is/are *47-68*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,288	04/08/2002	Claes Wallen	19497-011001 / P164881US00	2442

26191	7590	10/28/2008

FISH & RICHARDSON P.C.
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
DEAK, LESLIE R	
ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 10/28/2008

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 183 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 183 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

26161 7590 10/28/2008

FISH & RICHARDSON P.C.
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,288	04/08/2002	Claes Wallen	19497-011001 / P16488US00	2442

TITLE OF INVENTION: DEVICE AND METHOD FOR MIXING MEDICAL FLUIDS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$755	$300	$0	$1055	01/28/2009

EXAMINER	ART UNIT	CLASS-SUBCLASS
DEAK, LESLIE R	3761	604-403000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list
(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.
- ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

DETAILED ACTION

Allowable Subject Matter

1. Claims 47-68 are allowed.

2. The following is a statement of reasons for allowance: The prior art fails to disclose or suggest the device claimed by applicant.

Richmond discloses the apparatus substantially as claimed by applicant, but fails to disclose that port 182 is capable of receiving an injection needle for fluid infusion wherein the needle comprises a fluid transfer device, fluid reservoir, and additional membrane to form a double-bayonet coupling with the disclosed connector. Scislowicz teaches a snap fit coupling, but not a connector with the claimed inlet and outlet ports that are capable of functioning as claimed by applicant in combination with the claimed secondary fluid transfer device. Wood discloses a medical connector with a resilient connector member, but fails to disclose a connector with the claimed inlet and outlet ports that are capable of functioning as claimed by applicant in combination with the claimed secondary fluid transfer device. Leinsing discloses a medical adapter with fluid inlet and outlet ports, but fails to disclose or suggest the claimed secondary fluid transfer device.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner
Art Unit 3761
22 October 2008

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,288	04/08/2002	Claes Wallen	47865.272600	2442

28694 7590 10/04/2006

NOVAK DRUCE & QUIGG, LLP
1300 EYE STREET NW
400 EAST TOWER
WASHINGTON, DC 20005

EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/063,288	WALLEN ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3 and 6-22* is/are rejected.

7)☒ Claim(s) *2,4 and 5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 April 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination

1. Applicant's petition to withdraw abandonment filed 27 December 2005 was approved, and the following is a non-final action rejecting the claimed invention.

Claim Objections

2. Claim 16 is objected to because of the following informalities: It is unclear whether applicant intends to claim the combination of the device of claim 1 along with an injection needle and the fluid transfer device and fluid reservoir as set forth in the claim. Examiner has interpreted the claim to exclude the injection needle and fluid transfer device, since applicant has not positively claimed them as a portion of the claimed invention and has recited them merely as capable of use with the currently claimed mixing device. Appropriate correction is required.

3. Claim 21 is objected to because of the following informalities: It is unclear what, exactly, applicant is claiming as a portion of his device. Applicant claims the device of claim 1, "said device only comprising..." several elements. It is unclear whether applicant is intending to add or subtract limitations from the claim. Examiner has interpreted the claim to incorporate all the limitations of claim 1 and the structural features set forth in claim 21, omitting the restrictions inferred by the word "only." Appropriate correction is required.

4. Claim 22 is objected to because of the following informalities: It is unclear whether applicant intends to claim the combination of the device of claim 1 along with a

drip chamber of an infusion line. Applicant claims that the device is attached to a drip chamber, but does not set forth any limitations with regard to the drip chamber. As such, it is unclear whether applicant is claiming the combination of the claimed device with a drip chamber. Examiner has interpreted the claim to include the combination of the claimed device with the drip chamber, since applicant has recited that the device is attached to the drip chamber. Appropriate correction is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 3, 6-10, and 14-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,445,630 to Richmond in view of US 5,766,211 to Wood.

In the specification and figures, Richmond discloses the device as claimed by applicant. With regard to claims 1 and 9, Richmond discloses a device that is capable of mixing medical fluids comprising ports that may be used as an inlet port, injection port, and outlet port, respectively (see drawing, as annotated by Examiner, below, FIG 6). The device comprises a first duct 180 that extends between the inlet port and the injection port, and a second duct that extends between the inlet port and the outlet port (see FIG 6). The injection port comprises a hydrophobic, or fluid-proof membrane 182 that is capable of being penetrated by another device (see column 6, lines 18-53). The

device further comprises a first portion that houses the inlet port and the injection port and a second portion that houses the outlet port. Richmond illustrates that the portions are separate through the use of diagonal lines, indicating that the portions may be made of different materials.

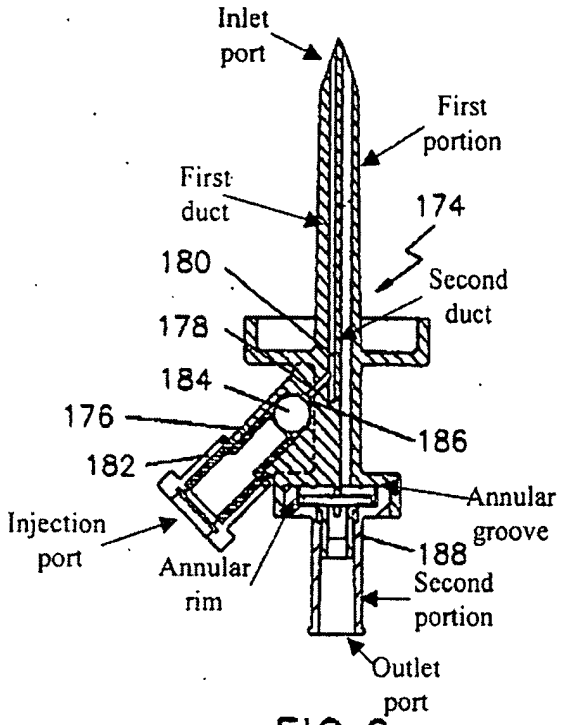


FIG.6.

With regard to applicant's recitation of the type of connection between the first and second portions, such a statement is held by the examiner to be a statement of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, applicant has failed to set forth any structural limitations that define the claimed connection. The Richmond device appears to have a friction fit between the first and second portions, which may snap into place. Absent any defining structural characteristics, the Richmond device is capable of operating as claimed by applicant, meeting the limitations of the claim.

Richmond is silent with regard to the materials used to construct the second part of the connector. However, Wood discloses a medical fluid mixing connector that comprises a rigid housing 12 and connecting cylinders 25, 5, and 6, made of an elastic material such as rubber (see Wood, column 5, lines 54-59, column 6, lines 36-45). The elastic material allows for airtight seals between the rigid and non-rigid portions of the device and simplifies connections (see column 6, lines 36-45). It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP 2144.07. In the instant case, Richmond illustrates that the connector is composed of two pieces, and Wood discloses a fluid mixing connector with a rigid portion and an elastomeric portion in order to create airtight seals. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the second portion of the Richmond device out of an elastomeric material as disclosed by Wood, in order to create an airtight seal and simplify connections, as taught by Wood (see column 6, lines 36-45).

With regard to claim 3, Richmond illustrates that the second portion of the connector comprises a tube section that extends downward from the connection with the first section, wherein the tube comprises a male luer fitting that is capable of receiving a male luer fitting that displaces the valve, such that the male luer fitting corresponds to the piercing member claimed by applicant. With regard to applicant's recitation of a second retention force, such a statement is held by the examiner to be a statement of the intended use of the device. It has been held that a recitation with

respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, applicant has failed to set forth any structural limitations that create a second retention force, and it appears that the connection between the female and male luer connectors of the Richmond device is retained by some force, meeting the limitations of the claim.

With regard to claims 6 and 15, Richmond discloses that the outlet port is sealed by a barrier or valve disk 170 that may be deformed by a male luer fitting or piercing element, opening a passage within the disk 170 (see column 6, lines 28-42).

With regard to claim 7, Richmond teaches that the connector comprises a polyethylene or other biocompatible plastic material, but is silent as to the method of molding. The claimed phrase "wherein said first portion has been injection molded from a thermoplastic polymer material" is being treated as a product by process limitation; that is, that the connector is made by injection molding. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 U.S.C.102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113. Thus, even though Richmond is silent as to the process used to mold the connector, it appears that the product in Richmond would be the same or similar as that claimed; especially since both applicant's product and the prior art product is made of a thermoplastic polymer material (see column 3, lines 50-57).

With regard to claim 8, Richmond specifically discloses that the first portion of the connector may be made of polyethylene (see column 3, lines 51-55).

With regard to claim 10, Richmond illustrates that the inlet port area comprises a spike 10 that is configured for puncturing the membrane 14 of an IV bag 16 (see column 3, lines 59-67).

With regard to claim 14, Richmond discloses that the outlet port is sealed by valve member 170, but fails to disclose that the valve is integral with and made of the same material as the outlet port (see column 6, lines 28-42). It has been held that forming in one piece an article that was formerly been formed in two pieces and put together involves only routine skill in the art. See MPEP 2144.04. Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP 2144.07. In the instant case, it would have been obvious to a worker in the art to form the barrier disclosed by Richmond integrally with the outlet port, necessarily forming both of the same material, since both modifications are recognized as a matter of obvious design choice.

With regard to claim 16, as interpreted by the Examiner, applicant's claim limitations amount to a recitation of the intended use of the device, since applicant fails to positively set forth the combination of the fluid mixing device and the injection needle with fluid transfer device, reservoir, and membrane. As such, it is the position of the examiner that the connector disclosed by Richmond comprises an outlet port with a

hydrophobic or fluid-proof membrane that is capable of being penetrated by a needle, meeting the limitations of the claims.

With regard to claim 17, applicant's language drawn to the function of the base member is held by the examiner to be a statement of the intended use of the base member. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, Richmond discloses that the device comprises flanges 40, 42 (see FIG 1) that are capable of supporting the device when it is in a horizontal position, meeting the limitations of the claims (see column 4, lines 23-33).

With regard to claim 18, Richmond discloses that the device comprises flanges 40, 42 (see FIG 1) that may be gripped by a user, meeting the limitations of the claim.

With regard to claim 19, Richmond discloses that the device may comprise a cap (not shown, see column 4, lines 23-33).

With regard to claim 20, Richmond illustrates that the connector comprises two portions attached to one another, meeting the limitations of the claim.

With regard to claim 21 as interpreted by the examiner, Richmond discloses that the connector comprises a first portion, second portion, hydrophobic membrane, and a cap or removable hood (see FIG 6, column 3, lines 23-33).

With regard to claim 22 as interpreted by the examiner, Richmond discloses that the connector may be attached to a drip chamber (see column 1, lines 20-25).

7. Claims 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,445,630 to Richmond in view of US 6,142,446 to Leinsing

In the specification and figures, Richmond discloses the device substantially as claimed by applicant (see rejection above) with the exception of a locking or hook member on the connector that engages with a secondary fluid container. Examiner considers the locking member and hook member to be similar in scope such that they both read on the Leinsing disclosure. Leinsing discloses a medical connector with a body 110 and a cannula 122 that may be inserted into a container 138 of medical fluid (see FIG 18). The body comprises claws 118 that correspond to applicant's locking member or hook member. The claws engage the neck of the secondary container to prevent disengagement of the spike from the container (see column 11, lines 31-57). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add the claws as disclosed by Leinsing to the connector as disclosed by Richmond in order to maintain a connection between the connector and a secondary fluid container, as taught by Leinsing (see column 11, lines 31-57).

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,445,630 to Richmond in view of US 6,146,362 to Turnbull et al.

In the specification and figures, Richmond discloses the device substantially as claimed by applicant (see rejection above) with the exception of a barb member on the connector that engages the interior surface of a fluid transfer port. Turnbull discloses a lfuid transfer device with a fluid transfer spike or key 12 with a retaining ring or barb 50 on the surface of the spike (see column 4, lines 43-65). When the spike is inserted into

a fluid transfer port of an injection port 10, the protrusion engages the interior of the fluid port 10, preventing retraction of the spike 12 from the port (see column 4, lines 43-65). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a barb member as disclosed by Turnbull to the spkied connector disclosed by Richmond in order to prevent disengagement of the spike from a fluid transfer port, as taught by Turnbull (see column 4, lines 43-65).

Allowable Subject Matter

9. Claims 2, 4, and 5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggest the device claimed by applicant.

With regard to claim 2, the prior art fails to disclose or suggest the connector of claim 1 along with the combination of a tapered groove and rim and complimentary snap-fit members. While Richmond discloses a groove and a rim, the reference fails to disclose tapering or a snap-fit member.

With regard to claim 4, the prior art fails to disclose or suggest the device of claim 1 in combination with the tube having a diameter structure as claimed by applicant.

With regard to claim 5, the prior art fails to disclose or suggest the device of claim 1 along with the combination of a tapered groove and rim and complimentary snap-fit

members. While Richmond discloses a groove and a rim, the reference fails to disclose tapering or a snap-fit member.

Response to Arguments

11. Applicant's amendment dated 27 December 2005 has been entered and considered. Applicant's amendment has corrected the 35 USC 112 issue in claim 17. Accordingly, the rejection has been withdrawn.

12. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

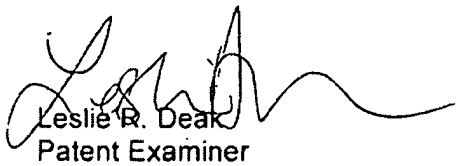
a. US 5,071,413 Utterberg

i. Universal connector

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie R. Deak
Patent Examiner
Art Unit 3761

Notice of References Cited	Application/Control No. 10/063,288	Applicant(s)/Patent Under Reexamination WALLEN ET AL.	
	Examiner Leslie R. Deak	Art Unit 3761	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,445,630	08-1995	Richmond, Frank M.	604/411
*	B	US-6,142,446	11-2000	Leinsing, Karl R.	251/149.1
*	C	US-6,146,362	11-2000	Turnbull et al.	604/256
*	D	US-5,071,413	12-1991	Utterberg, David S.	604/533
*	E	US-5,766,211	06-1998	Wood et al.	604/32
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,288	04/08/2002	Claes Wallen	6730.020.NPUS00	2442

28694 7590 06/15/2007
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EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
06/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

HH

Office Action Summary	Application No.	Applicant(s)	
	10/063,288	WALLEN ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,6-15 and 17-22* is/are rejected.

7)☒ Claim(s) *2,4,5,16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 April 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 3, 6-10, and 14-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,445,630 to Richmond in view of US 5,766,211 to Wood.

In the specification and figures, Richmond discloses the device as claimed by applicant. With regard to claims 1 and 9, Richmond discloses a device that is capable of mixing medical fluids comprising ports that may be used as an inlet port, injection port, and outlet port, respectively (see drawing, as annotated by Examiner, below, FIG 6). The device comprises a first duct 180 that extends between the inlet port and the injection port, and a second duct that extends between the inlet port and the outlet port (see FIG 6). The injection port comprises a hydrophobic, or fluid-proof membrane 182 that is capable of being penetrated by another device (see column 6, lines 18-53). The device further comprises a first portion that houses the inlet port and the injection port and a second portion that houses the outlet port. Richmond illustrates that the portions are separate through the use of diagonal lines, indicating that the portions may be made of different materials.

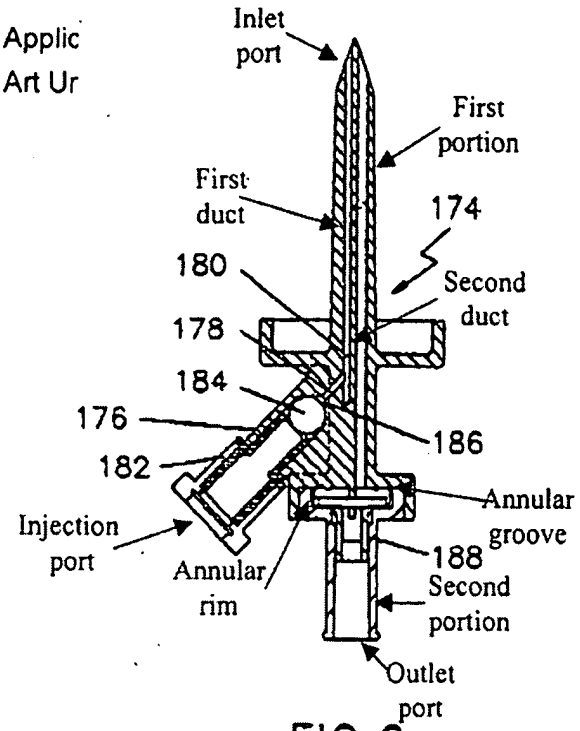

FIG.6.

With regard to applicant's recitation of the type of connection between the first and second portions, such a statement is held by the examiner to be a statement of the function of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, applicant has failed to set forth any structural limitations that define the claimed connection. The Richmond device appears to have a friction fit between the first and second portions, which may snap into place. Absent any defining structural characteristics, the Richmond device is capable of operating as claimed by applicant, meeting the limitations of the claim.

Richmond is silent with regard to the materials used to construct the second part of the connector. However, Wood discloses a medical fluid mixing connector that comprises a rigid housing 12 and connecting cylinders 25, 5, and 6, made of an elastic material such as rubber (see Wood, column 5, lines 54-59, column 6, lines 36-45). The elastic material allows for airtight seals between the rigid and non-rigid portions of the

device and simplifies connections (see column 6, lines 36-45). It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP 2144.07. In the instant case, Richmond illustrates that the connector is composed of two pieces, and Wood discloses a fluid mixing connector with a rigid portion and an elastomeric portion in order to create airtight seals. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the second portion of the Richmond device out of an elastomeric material as disclosed by Wood, in order to create an airtight seal and simplify connections, as taught by Wood (see column 6, lines 36-45).

With regard to claim 3, Richmond illustrates that the second portion of the connector comprises a tube section that extends downward from the connection with the first section, wherein the tube comprises a male luer fitting that is capable of receiving a male luer fitting that displaces the valve, such that the male luer fitting corresponds to the piercing member claimed by applicant. With regard to applicant's recitation of a second retention force, such a statement is held by the examiner to be a statement of the function of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, applicant has failed to set forth any structural limitations that create a second retention force, and it appears that

the connection between the female and male luer connectors of the Richmond device is retained by some force, meeting the limitations of the claim.

With regard to claims 6 and 15, Richmond discloses that the outlet port is sealed by a barrier or valve disk 170 that may be deformed by a male luer fitting or piercing element, opening a passage within the disk 170 (see column 6, lines 28-42).

With regard to claim 7, Richmond teaches that the connector comprises a polyethylene or other biocompatible plastic material, but is silent as to the method of molding. The claimed phrase "wherein said first portion has been injection molded from a thermoplastic polymer material" is being treated as a product by process limitation; that is, that the connector is made by injection molding. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 U.S.C.102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113. Thus, even though Richmond is silent as to the process used to mold the connector, it appears that the product in Richmond would be the same or similar as that claimed; especially since both applicant's product and the prior art product is made of a thermoplastic polymer material (see column 3, lines 50-57).

With regard to claim 8, Richmond specifically discloses that the first portion of the connector may be made of polyethylene (see column 3, lines 51-55).

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With regard to claim 14, Richmond discloses that the outlet port is sealed by valve member 170, but fails to disclose that the valve is integral with and made of the same material as the outlet port (see column 6, lines 28-42). It has been held that forming in one piece an article that was formerly been formed in two pieces and put together involves only routine skill in the art. See MPEP 2144.04. Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP 2144.07. In the instant case, it would have been obvious to a worker in the art to form the barrier disclosed by Richmond integrally with the outlet port, necessarily forming both of the same material, since both modifications are recognized as a matter of obvious design choice.

With regard to claim 17, applicant's language drawn to the function of the base member is held by the examiner to be a statement of the intended use of the base member. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, Richmond discloses that the device comprises flanges 40, 42 (see FIG 1) that are capable of supporting the device when it is in a horizontal position, meeting the limitations of the claims (see column 4, lines 23-33).

With regard to claim 18, Richmond discloses that the device comprises flanges 40, 42 (see FIG 1) that may be gripped by a user, meeting the limitations of the claim.

With regard to claim 19, Richmond discloses that the device may comprise a cap (not shown, see column 4, lines 23-33).

With regard to claim 20, Richmond illustrates that the connector comprises two portions attached to one another, meeting the limitations of the claim.

With regard to claim 21, Richmond discloses that the connector comprises a first portion, second portion, hydrophobic membrane, and a cap or removable hood (see FIG 6, column 3, lines 23-33).

With regard to claim 22, Richmond discloses that the connector may be attached to a drip chamber (see column 1, lines 20-25).

3. Claims 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,445,630 to Richmond in view of US 6,142,446 to Leinsing

In the specification and figures, Richmond discloses the device substantially as claimed by applicant (see rejection above) with the exception of a locking or hook member on the connector that engages with a secondary fluid container. Examiner considers the locking member and hook member to be similar in scope such that they both read on the Leinsing disclosure. Leinsing discloses a medical connector with a body 110 and a cannula 122 that may be inserted into a container 138 of medical fluid (see FIG 18). The body comprises claws 118 that correspond to applicant's locking member or hook member. The claws engage the neck of the secondary container to prevent disengagement of the spike from the container (see column 11, lines 31-57).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add the claws as disclosed by Leinsing to the connector as disclosed by Richmond in order to maintain a connection between the connector and a secondary fluid container, as taught by Leinsing (see column 11, lines 31-57).

4. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,445,630 to Richmond in view of US 6,146,362 to Turnbull et al.

In the specification and figures, Richmond discloses the device substantially as claimed by applicant (see rejection above) with the exception of a barb member on the connector that engages the interior surface of a fluid transfer port. Turnbull discloses a lfuid transfer device with a fluid transfer spike or key 12 with a retaining ring or barb 50 on the surface of the spike (see column 4, lines 43-65). When the spike is inserted into a fluid transfer port of an injection port 10, the protrusion engages the interior of the fluid port 10, preventing retraction of the spike 12 from the port (see column 4, lines 43-65). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a barb member as disclosed by Turnbull to the spiked connector disclosed by Richmond in order to prevent disengagement of the spike from a fluid transfer port, as taught by Turnbull (see column 4, lines 43-65).

Allowable Subject Matter

5. Claims 2, 4, 5, and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggest the device claimed by applicant.

With regard to claim 2, the prior art fails to disclose or suggest the connector of claim 1 along with the combination of a tapered groove and rim and complimentary snap-fit members. While Richmond discloses a groove and a rim, the reference fails to disclose tapering or a snap-fit member.

With regard to claim 4, the prior art fails to disclose or suggest the device of claim 1 in combination with the tube having a diameter structure as claimed by applicant.

With regard to claim 5, the prior art fails to disclose or suggest the device of claim 1 along with the combination of a tapered groove and rim and complimentary snap-fit members. While Richmond discloses a groove and a rim, the reference fails to disclose tapering or a snap-fit member.

With regard to claim 16, the prior art fails to disclose or suggest the connector of claim 1 in combination with a fluid transfer device, second medical fluid reservoir, wherein the connections form a double-membrane bayonet coupling as claimed, along with the other steps and limitations of the claims.

Response to Arguments

7. Applicant's amendment and arguments filed 5 February 2007 have been entered and considered. Applicant's amendments corrected the problems in claims 16, 21, and 22 and the corresponding objections have been withdrawn.

8. Applicant argues that Examiner has not made a *prima facie* case of obviousness over Richmond in view of Wood, since the references fail to teach two components formed of different materials and fail to teach the coupling claimed by applicant.

9. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, the prior art teaches or suggests the structural limitations of the claimed device and provides motivation for their combination. As such, the combination suggested by examiner is not a result of impermissible hindsight, but rather merely results from the teachings of the cited art.

10. Applicant argues that Richmond fails to disclose that the components of the device may be made of different materials. However, as noted in the Office Action, Richmond illustrates first portion 188 with one pattern of diagonal stripes and the second portion with a second pattern of diagonal stripes, indicating that the materials may be different. Applicant asserts that the Richmond disclosure teaches that the pieces are likely made from the same material because they are bonded together, which teaches away from the present invention. However, Examiner is not asserting that the Richmond device alone teaches the use of different materials in a multi-piece

connector. Examiner is using that particular figure of the Richmond device to show that the pieces are separate, providing the possibility that they may be formed of different materials, as taught by Wood.

11. Applicant further argues that Richmond's disclosure concerning the bonding of the pieces together teaches away from the claimed invention, which does not need adhesives to couple the pieces. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., coupling without any adhesive) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

12. Applicant argues that the recitation of a friction-fit and snap-fit coupling in the independent claim includes structural components. However, this is not the case. The structural components of a snap fit coupling include a protrusion coupled with a groove that snap into place. Applicant discloses such a snap connection 111, 112 in paragraph 0029 and FIG 3, but fails to set forth any structural limitations that distinguish the instantly claimed invention from the prior art. Apparatus claims cover what a device is, not what a device does. See MPEP 2114. Applicant points to Richmond's disclosure of bonding the pieces together to teach away from a friction fit. However, Richmond's disclosure with regard to the bonding applies to the embodiment shown in FIG 2, and Richmond is silent as to the type of connection of the embodiment shown in FIG 6. Therefore, it is the position of the examiner that the structural limitations of the claimed

device are disclosed in the prior art, rendering the instantly presented claim unpatentable over the prior art of record.

13. Applicant argues further that the first and second portions of the Wood device do not comprise the materials that make up the claimed "first" and "second" portions of the claimed device. However, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie R. Deak
Patent Examiner
Art Unit 3761
3 April 2007

PATRICIA BIANCO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

6/12/07

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,288	04/08/2002	Claes Wallen	47865.272600	2442

28694 7590 09/07/2005

NOVAK DRUCE & QUIGG, LLP
1300 EYE STREET NW
SUITE 400 EAST TOWER
WASHINGTON, DC 20005

EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Notice of Abandonment	Application No.	Applicant(s)	
	10/063,288	WALLEN ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

This application is abandoned in view of:

1. ☒ Applicant's failure to timely file a proper reply to the Office letter mailed on *04 February 2005*.
   (a) ☐ A reply was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply (including a total extension of time of _____ month(s)) which expired on _____.
   (b) ☐ A proposed reply was received on _____, but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection.
   (A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).
   (c) ☐ A reply was received on _____ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
   (d) ☒ No reply has been received.

2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
   (a) ☐ The issue fee and publication fee, if applicable, was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
   (b) ☐ The submitted fee of $_____ is insufficient. A balance of $_____ is due.
   The issue fee required by 37 CFR 1.18 is $_____. The publication fee, if required by 37 CFR 1.18(d), is $_____.
   (c) ☐ The issue fee and publication fee, if applicable, has not been received.

3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
   (a) ☐ Proposed corrected drawings were received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply.
   (b) ☐ No corrected drawings have been received.

4. ☐ The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.

5. ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.

6. ☐ The decision by the Board of Patent Appeals and Interference rendered on _____ and because the period for seeking court review of the decision has expired and there are no allowed claims.

7. ☐ The reason(s) below:

1 Sept 05

PATRICIA BIANCO
PRIMARY EXAMINER
9/2/05

Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
WALLÉN, Claes *et al.*

Serial No.: 10/063,288

Confirmation No.: 2442

Filed: 04/08/2003

For: DEVICE AND METHOD FOR MIXING MEDICAL FLUIDS

Group Art Unit: 3762

Examiner: DEAK, Leslie R.

Atty. Dkt. No.: 06730.0020.NPUS00

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO NON-FINAL OFFICE ACTION

Dear Sir:

The attached Response is being provided in response to the Non-Final Office Action mailed February 4, 2005.

THE CLAIMS:

1. (Original) A device for mixing medical fluids, said device comprising an inlet port for receiving at least a first medical fluid, an injection port for injection of a second medical fluid, an outlet port for exit of a mixed flow of said first and second medical fluids, a first duct extending between said injection port and said inlet port, and a second duct extending between said inlet port and said outlet port, said injection port being sealed by a fluid-proof membrane which can be penetrated by an injection needle when injecting said second medical fluid, at least a first portion made of a first material and a second portion made of a second material, wherein said second material is substantially more resilient than said first material, and said inlet port and said injection port are included in said first portion and said outlet port is included in said second portion wherein said first and second portions are attached to each other by means of a combined friction coupling and snap connection providing a first retention force.

2. (Original) The device according to claim 1, said first portion further comprising an annular, tapering groove and said second portion further comprising an annular, tapering rim, said first portion comprising a first snap member and said second portion comprising a second snap member, wherein said groove is designed and arranged for snugly accommodating said rim in order to provide part of said first retention force, and wherein said first snap member is designed and arranged for interacting with said second snap member in order to provide the remainder of said first retention force.

3. (Original) The device according to claim 1, said outlet port further comprising a tube of said resilient second material, wherein said tube is designed and arranged for snugly accommodating a piercing member of an infusion line in order to retain said piercing member with a second retention force.

4. (Original) The device according to claim 1, said outlet port further comprising a tube of said resilient second material, said tube having a first diameter at a first end facing towards said first portion and a second diameter at a second end facing towards said outlet port wherein said tube is designed and arranged with said second diameter being smaller than said first diameter in order to allow leakage-proof insertion of a piercing member of an infusion line.

5. (Original) The device according to claim 1, said first portion further comprising an annular, tapering groove, said second portion further comprising an annular, tapering rim, and said outlet port further comprising a tube of said resilient second material, wherein said groove is designed and arranged for retaining said rim with a first retention force and said tube is designed and arranged for retaining a piercing member of an infusion line with a second retention force in such a way that said first and second retention forces both are larger than 15 N in 30 seconds and said first retention force is larger than said second retention force.

6. (Original) The device according to claim 1, wherein said outlet port is sealed by a barrier member which is designed and arranged to be ruptured by a piercing member of an infusion line in order to open a passage for said mixed flow from said inlet port to said outlet port

7. (Original) The device according to claim 1, wherein said first portion has been injection-molded from a thermoplastic polymer material.

8. (Original) The device according to claim 1, wherein said first portion is made of polypropylene, polycarbonate or ABS-polymer.

9. (Original) The device according to claim 1, wherein said second portion is made of an elastomeric polymer material or a synthetic rubber material.

10. (Original) The device according to claim 1, said inlet port further comprising a rigid spike member for penetrating a fluid-proof septum of a fluid container containing said first medical fluid.

11. (Original) The device according to claim 1, said first portion further comprising a locking member for permanent coupling to a fluid transfer port of a fluid container containing said first medical fluid.

12. (Original) The device according to claim 1, said inlet port further comprising a rigid spike member having at least one barb member for engaging an internal surface of a fluid transfer port of a fluid container containing said first medical fluid.

13. (Original) The device according to claim 1, said inlet port further comprising a rigid spike member having at least one hook member for engaging an external surface of a fluid transfer port of a fluid container containing said first medical fluid.

14. (Original) The device according to claim 1, said outlet port being sealed by a barrier member which is integrated with and made of the same material as said outlet port.

15. (Original) The device according to claim 1, wherein said outlet port is sealed by a barrier member which is designed and arranged to be ruptured by a piercing member of an additional spike member in order to enable passage of said mixed flow from said Inlet port via said second duct through said additional spike member into an infusion line.

16. (Original) The device according to claim 1, wherein said fluid-proof membrane of said injection port is designed and arranged to be penetrated by said injection needle, wherein said injection needle is provided by a fluid transfer device which can be connected to a second medical fluid-reservoir at one end and which exhibits an additional fluid-proof membrane at the other end which is designed and arranged to be included in a double-membrane bayonet coupling with said injection port.

17. (Currently Amended) The device according to claim 1, ~~characterized in that the~~ wherein said device ~~exhibits~~ comprises a base member ~~for allowing~~ that supports the device ~~to rest~~ in a horizontal position before infusion.

18. (Original) The device according to claim 1, said device further comprising a handle grip for facilitating connection of said device to a fluid container.

19. (Original) The device according to claim 1, said second portion further comprising a cap member for preventing contamination which can be opened in order to access said outlet port.

20. (Original) The device according to claim 1, wherein said device has less than five components attached to each other.

21. (Original) The device according to claim 1, said device only comprising said fluid-proof membrane, said first portion, said second portion, and a removable hood for preventing contamination of said inlet port.

22. (Original) The device according to claim 1, wherein said second portion of said device is attached to a drip chamber of an infusion line

23-45. (Cancelled)

REMARKS:

REMARKS REGARDING ELECTION:

It is respectfully pointed out that claims 23-45 which are subject to restriction had previously not been cancelled, but instead had been withdrawn. In view of the finality of the requirement, however, these claims have now been cancelled.

REMARKS REGARDING CLAIMS AMENDMENTS:

Claim 17 has been amended to remedy the rejection under 35 U.S.C. § 112, second paragraph and thus it is requested that Examiner reconsider and withdraw the rejection of the claim on that basis.

IN RESPONSE TO THE OFFICE ACTION:

REJECTIONS UNDER 35 U.S.C. § 103:

Claims 1-22 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Richmond (US 5445630).

Applicants request that Examiner reconsider and withdraw the above rejection of the claims in view of the following:

By way of background, it should be appreciated that devices configured according to the teachings of the present invention are mixing devices which comprise a first portion and a second portion, each of which are made of different materials and connected to each other by means of a combined friction coupling and snap connection.

An accordingly configured device enables mixing of medical fluids. The first portion has a spike with an inlet port 101 and can be connected to an infusion bag comprising a first medical substance. Injection of a second medical substance can be performed by use of an injection needle penetrating a fluid-proof membrane 106 of an injection port 102.

The second portion provides an outlet port 103 for exit of a mixed flow of the first and second medical fluids.

Because of the division of the device into the first and second portions, the second portion can advantageously be constructed from an elastomeric polymer material that is more resilient than the material of the first portion which may exemplarily and advantageously be constructed from a thermoplastic polymer material. The ability to utilize such diverse materials affords several important beneficial functions.

Among others, this special coupling enables the device to be assembled from a minimum of individual components without any use of glue or adhesive. The less resilient material of the first component ensures that the inlet and injection ports are sufficiently shape-permanent during use, whereas the more resilient material of the second portion is capable of providing the requisite sealing action between the first and second portions, and between the second portion and an additional component.

Another attribute of utilizing a more resilient material for the second portion is that an additional component can be connected to the device (see Fig. 4) in a similar way as the first portion is connected to the infusion bag. Thus, the second portion allows leak-proof insertion of a rigid spike (which could be the first portion of a further device according to the invention) into the outlet port in order to create an infusion line, for instance.

Furthermore, the device can be adapted for several applications by combining the first portion with differently designed second portions.

Now turning to US 5,445,630 issued to Richmond: as an initial point, Richmond '630 does not describe a mixing device as expressly recited by Applicant.

Moreover, the port 176 which Examiner has cited as an "injection port" is in fact not an injection port, but is instead only a ventilation channel. More particularly, the "spike" of Richmond '630 is vented as described therein at column 6, lines 38-52 (see excerpt immediately below).

(*Richmond '630, column 6, lines 38-52*) FIG. 6 shows a spike 174 which is a vented spike, i.e., the spike 174 has a gas tube 176 defining a gas passageway 178, and the gas passageway 178 is in fluid communication with a first fluid passageway 180 of the spike 174.

Preferably, a hydrophobic membrane 182 is positioned athwart the gas passageway 178, and a ball 184 is positioned for reciprocating movement within the gas passageway 178. The ball 184 can contact a seat 186 that is formed in the gas tube 176 to block fluid flow through the gas passageway 178. On the other hand, gas within the fluid passageway 180 will urge the ball 184 away from the seat 186 to permit the gas to pass out of the fluid passageway 180 through the gas passageway 178 and hydrophobic membrane 182. The spike 174 also has a female luer fitting with valve 188.

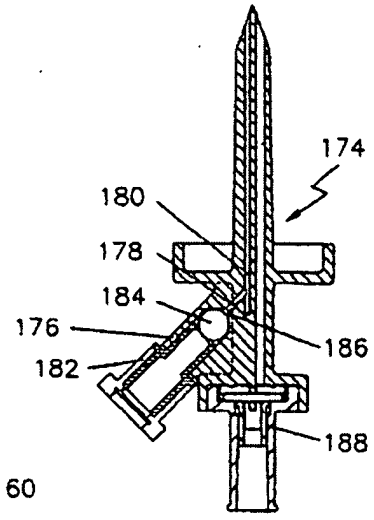


FIG.6.

The other port has a first luer fitting portion with a valve to permit fluid flow through the spike when a corresponding second luer fitting portion is engaged to the first luer fitting portion and to prevent fluid flow through the spike when the second luer fitting portion is not connected to the first.

It must be appreciated that luer fittings are well known in the art as being standard components in which a first luer fitting portion and a second luer fitting portion are conical fittings with or without a thread. Therefore, it is respectfully asserted that such a luer fitting as stated by the Examiner cannot constitute a second portion of the device and be regarded as a combined friction coupling and snap connection between a first and a second portion of a resulting device.

Still further, there is no citation supporting Examiner's position that it would be obvious to a person skilled in the art to separate the one-piece spike device of Richmond '630 into two portions, which portions are connectable to each other by means of a combined friction and snap connection as expressly recited by Applicant. Moreover, the one piece construction of Richmond '630 amounts to a "teaching away" from the two-portion construction recited by Applicant, and particularly the two-portion construction wherein the second portion is constructed from material that is more resilient than the material of the first portion, which are intended to be connectable to each other by a combined friction and snap connection.

Equally as important is the fact that the device of Richmond '630 would be rendered unworkable if divided into two portions as recited by Applicant, but connected to each other by a combined friction and snap connection; specifically, it would not be possible to make the luer fitting from a more resilient material in accordance Applicant's recited invention because the luer fitting has to be made of a relatively hard rigid material to ensure proper functioning.

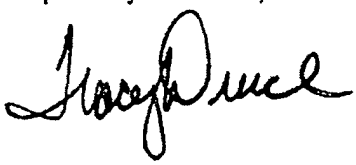
In view of the above, Applicant submits that the requirement and burden of presenting of a *prima facie* case of obviousness under 35 USC §103 has not been presented. Therefore Applicant requests reconsideration and withdrawal of the rejection of the claims under 35 USC §103.

It is believed that the above amendments and remarks place the application in condition for allowance. Therefore, a Notice of Allowance is respectfully solicited.

The undersigned representative authorizes the Commissioner to charge any additional fees under 37 C.F.R. 1.16 or 1.17 that may be required, or credit any overpayment, to Deposit Account No. 14-1437, referencing Order No. 06730.0020.NPUS00.

In order to facilitate the resolution of any issues or questions presented by this paper, the Examiner should directly contact the undersigned by phone to further the discussion.

Respectfully submitted,



Tracy W. Druce
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3762

PTO/SB/21 (09-04)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	10/063,288
Filing Date	04/08/2003
First Named Inventor	WALLEN
Art Unit	3762
Examiner Name	DEAK
Attorney Docket Number	06730.0020.NPUS00

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):
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Remarks

Re-submission of previous Reply including return receipt ackknowledgement.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	NOVAK DRUCE & QUIGG, LLP		
Signature			
Printed name	Tracy W. Druce		
Date	12/23/2005	Reg. No.	35,493

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name	Tracy W. Druce	Date	12/23/2005

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	10/063,288
Filing Date	4/8/03
First Named Inventor	Walker
Art Unit	
Examiner Name	Deak
Attorney Docket Number	6730.0020.NPUS00

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☒ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☒ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
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- ☐ Power of Attorney, Revocation Change of Correspondence Address
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- Post Card
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PTO/SB/22 (10-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)

Docket Number (Optional): 06730.0020.NPUS00

In re Application of: WALLEN

Application Number: 10/063,288 | Filed: 04/08/2003

For: Device And Method For Mixing Medical Fluids

Group Art Unit: 3762 | Examiner: DEAK, Leslie R.

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and appropriate non-small-entity fee are as follows (check time period desired):

- ☐ One month (37 CFR 1.17(a)(1)) $_____
- ☐ Two months (37 CFR 1.17(a)(2)) $_____
- ☑ Three months (37 CFR 1.17(a)(3)) $ 510.00
- ☐ Four months (37 CFR 1.17(a)(4)) $_____
- ☐ Five months (37 CFR 1.17(a)(5)) $_____

☑ Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee amount shown above is reduced by one-half, and the resulting fee is: $ 510.00.

☐ A check in the amount of the fee is enclosed.

☑ Payment by credit card. Form PTO-2038 is attached.

☐ The Commissioner has already been authorized to charge fees in this application to a Deposit Account.

☑ The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 141437. I have enclosed a duplicate copy of this sheet.

I am the ☐ applicant/inventor

☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

☑ attorney or agent of record.

☐ attorney or agent under 37 CFR 1.34(a). Registration number if acting under 37 CFR 1.34(a)_____.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

07/20/2005
Date

Signature

Tracy W. Druce
Typed or printed name

12/29/2005 EABRAHA1 00000019 10063288
01 FC:2253 510.00 OP

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☐ Total of _____ forms are submitted.